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From: Stephen Morrissey [stephen@botanica-bioscience.com]
Sent: Tuesday, July 27, 1999 8:08 PM
To: FDADockets@oc.fda.gov
Subject: Defining Disease under DSHEA

TO: DOCKETS MANAGEMENT BRANCH OF FDA
RE: PROPOSED DEFINITION OF "DISEASE" UNDER DSHEA
DATE: JULY 27, 1999

DEFINING "DISEASE"

For the purposes of current discussions regarding FDA implementation of DSHEA, it would be most appropriate and more accurate to assess the definition of "disease" in the context of a broader perspective that also defines "health".

Dynamic systems such as the human body, which manifest the processes inherent in all living systems, undergo fluctuations as part of their "normal" experience. The severity and chronicity of deviations from a normal flux pattern will lead to and manifest as functional or structural disorders to varying degrees in each individual. There is no determinate amount of flux abnormality that will cause disease. This is due to the fact that individuals vary in their capacity to compensate for abnormal flux. Those with weaker constitutions may be more susceptible to quantitative variations whereas those that are "unbalanced" yet strong may be more susceptible to qualitative variations.

Physiological and metabolic changes which result in "disease" often manifest as "sub-clinical" disorders prior to becoming a "clinical" disorder which is then labeled as a "disease". For example, heartburn, bloating, or belching may precede a more serious or long term flux abnormality such as chronic gastritis. Would the attempted amelioration of a flux abnormality such as belching and bloating using herbal products represent "disease" treatment? Probably not. Yet the bloating may represent the same condition, though less severe than the gastritis. The same herbal ingredients that aleviate the bloating may also be an appropriate way to ameliorate the symptoms of gastritis. Wouldn't it benefit the consumer to state the appropriate use of the product, even if it IS gastritis, if based on and backed by clinical research, with labeling included which states: "If the condition persists for more than a ?? then we recommend you seek professional medical advice."

At what point does the "flux abnormality" cross over into a condition defined as a "disease"? Clearly there is a gray area between normal flux and clinical "disease". Defining this gray area may be difficult, but in the long run, the abnormal flux patterns in that gray area are where well designed natural health products can provide the most appropriate and substantial benefits to our citizenry. Therefore, sadly for those implementing DSHEA, defining disease in concrete terms is neither practical nor appropriate toward the sometimes conflicting goal of protecting and assisting the consumer.

Clearly the issue of addressing nutritional deficiencies with vitamins and minerals is only distantly related to the issue of managing flux abnormalities using metabolic and physiological regulators such as herbal

ingredients. The evolution of the regulatory guidelines for natural health products must continue to add clarity beyond the initial guidelines provided under DSHEA. That bill was just a first, although great and vital step in the right direction. However the Congress needs to help the FDA and natural products industry by adding additional clarity to the 1994 law.

My sincere and best wishes for thoughtful progress,
Stephen Morrissey OMD
Ketchum, Idaho